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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,868	07/28/2003	Joo Hwan Yang	P66230US1	3627
136	7590	10-12/2004	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			NOLAN, SANDRA M	
			ART UNIT	PAPER NUMBER
			1772	

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/627,868	Applicant(s) YANG, JOO HWAN	
	Examiner Sandra M. Nolan	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims

1. Claims 1-3 are pending.

Priority

2. The priority statement in the preliminary amendment dated 28 July 2003 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al (US 6,309,663; filed 17 August 1999) in view of Stroppolo et al (US 5,869,102) or Corbo et al (US 6,551,617).

Patel teaches combined surfactants in dosage forms (col. 54, lines 57 and 62) that have enhanced absorption of drugs (abstract). The surfactants include diacetylated

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monoglycerides (col. 16, lines 13-14) and sodium lauryl sulfate (col. 22, lines 23). The dosage forms may be hard gelatin capsules (col. 76, line 52).

It fails to teach colloidal silica.

Stroppolo teaches, in its abstract, that colloidal silica is a disintegrating agent in dosage forms (abstract).

Corbo teaches, at col. 5, lines 1-3, colloidal silica and SLS as processing aids in coatings for hard gelatin capsules (col. 5, lines 18-20).

The references are analogous because they all deal with dosage forms.

It would have been obvious to one having ordinary skill in the art at the time of the invention to employ the colloidal silica of Stroppolo or Corbo in the dosage forms of Patel as a disintegrant or processing aid, in order to improve the properties of the resultant dosage forms.

The motivation to employ the colloidal silica of Stroppolo in the dosage forms of Patel is found in the Stroppolo abstract, where the use of silica as a disintegrant is taught.

The motivation to employ the colloidal silica of Corbo in the dosage forms of Patel is found in at col. 5, lines 1-3 of Corbo, where it teaches that colloidal silica is a processing aid.

It is deemed desirable to make dosage forms in which the dosage forms disintegrate readily (per Stroppolo) and/or are easily made (per Corbo) in order to facilitate drug delivery or simplify manufacturing, respectively.

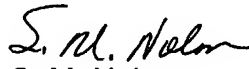
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Conclusion

Any inquiry concerning this communication should be addressed to Sandra M. Nolan, at telephone number 571/272-1495. She can normally be reached Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

If attempts to reach the examiner are unsuccessful, her supervisor, Harold Pyon, can be reached at 571/272-1498.

The fax number for patent application documents is 703/872-9306.


S. M. Nolan
Primary Examiner
Technology Center 1700

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